

**Public Health Goal for
DALAPON
in Drinking Water**

Prepared by

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PREFACE

Drinking Water Public Health Goal of the Office of Environmental Health Hazard Assessment

This Public Health Goal (PHG) technical support document provides information on health effects from contaminants in drinking water. The PHG describes concentrations of contaminants at which adverse health effects would not be expected to occur, even over a lifetime of exposure. PHGs are developed for chemical contaminants based on the best available toxicological data in the scientific literature. These documents and the analyses contained in them provide estimates of the levels of contaminants in drinking water that would pose no significant health risk to individuals consuming the water on a daily basis over a lifetime.

The California Safe Drinking Water Act of 1996 (amended Health and Safety Code, Section 116365) requires the Office of Environmental Health Hazard Assessment (OEHHA) to adopt PHGs for contaminants in drinking water based exclusively on public health considerations. The Act requires OEHHA to adopt PHGs that meet the following criteria:

1. PHGs for acutely toxic substances shall be set at levels at which scientific evidence indicates that no known or anticipated adverse effects on health will occur, plus an adequate margin-of-safety.
2. PHGs for carcinogens or other substances which can cause chronic disease shall be based solely on health effects without regard to cost impacts and shall be set at levels which OEHHA has determined do not pose any significant risk to health.
3. To the extent the information is available, OEHHA shall consider possible synergistic effects resulting from exposure to two or more contaminants.
4. OEHHA shall consider the existence of groups in the population that are more susceptible to adverse effects of the contaminants than a normal healthy adult.
5. OEHHA shall consider the contaminant exposure and body burden levels that alter physiological function or structure in a manner that may significantly increase the risk of illness.
6. In cases of scientific ambiguity, OEHHA shall use criteria most protective of public health and shall incorporate uncertainty factors of noncarcinogenic substances for which scientific research indicates a safe dose-response threshold.
7. In cases where scientific evidence demonstrates that a safe dose-response threshold for a contaminant exists, then the PHG should be set at that threshold.
8. The PHG may be set at zero if necessary to satisfy the requirements listed above.
9. OEHHA shall consider exposure to contaminants in media other than drinking water, including food and air and the resulting body burden.
10. PHGs adopted by OEHHA shall be reviewed periodically and revised as necessary based on the availability of new scientific data.

PHGs adopted by OEHHA are for use by the California Department of Health Services (DHS) in establishing primary drinking water standards (State Maximum Contaminant Levels, or MCLs). Whereas PHGs are to be based solely on scientific and public health considerations without regard to economic cost considerations, drinking water standards adopted by DHS are to consider economic factors and technical feasibility. For this reason PHGs are only one part of the

information used by DHS for establishing drinking water standards. PHGs established by OEHHA exert no regulatory burden and represent only non-mandatory goals. By federal law, MCLs established by DHS must be at least as stringent as the federal MCL if one exists.

PHG documents are developed for technical assistance to DHS, but may also benefit federal, state and local public health officials. While the PHGs are calculated for single chemicals only, they may, if the information is available, address hazards associated with the interactions of contaminants in mixtures. Further, PHGs are derived for drinking water only and are not to be utilized as target levels for the contamination of environmental waters where additional concerns of bioaccumulation in fish and shellfish may pertain. Often environmental water contaminant criteria are more stringent than drinking water PHGs, to account for human exposures to a single chemical in multiple environmental media and from bioconcentration by plants and animals in the food chain.

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SUMMARY

A Public Health Goal (PHG) of 790 ppb is developed for dalapon in drinking water. U.S. Environmental Protection Agency's (U.S. EPA's) Maximum Contaminant Level (MCL) is 200 ppb. Dalapon is not currently registered for use as a pesticide active ingredient in California. We calculated a PHG for dalapon of 790 ppb based on an adjusted no-observed-adverse-effect-level (NOAEL) of 8.45 mg/kg-day for increased kidney-to-body weight ratio in male rats, an uncertainty factor of 300 and a relative source contribution of 80%. Therefore, OEHHA calculates a PHG of 0.79 mg/L (790 ppb) for dalapon in drinking water.

INTRODUCTION

Dalapon, either as the free acid (2,2-dichloropropionic acid) or salt (sodium or magnesium 2,2-dichloropropionate) was once used in California as an herbicide. This material had numerous uses but was used predominantly as an industrial/noncrop herbicide. Agricultural use of dalapon (less than 30% of the total use) was for the control of various grasses in sugarcane and potatoes. Dalapon is not currently registered as an active pesticide ingredient in California.

TOXICOLOGY

A search of the scientific literature was conducted to determine if any new toxicological information concerning dalapon had been published since U.S. EPA's 1992 Drinking Water Quality Criteria Document (U.S. EPA, 1992b).¹ No new information is available regarding the toxicity of dalapon that would aid in the development of a new PHG.

Three chronic toxicity studies (of one year or more years duration) are available for dalapon (Dow, 1983; Paynter *et al.*, 1960). The Dow study is a two-year dietary study in mice that identified an NOAEL of 60 mg/kg-day (salt) based on increased relative kidney weights.

Paynter *et al.* (1960) administered 0, 15 or 50 mg commercial dalapon sodium salt/kg body weight/day in the diet of albino Carworth rats (24 male, 24 female/group) for two years. Hematological parameters were examined at timed intervals and histopathology was performed at 104 weeks. A statistically significant ($p < 0.05$) increase over controls was observed in the kidney-to-body weight ratio of male rats receiving 50 mg/kg-day. No other differences from controls were observed. Kidney lesions were not observed in the treated animals. A second study reported by Paynter *et al.* (1960) is a one-year feeding study in dogs. The endpoint of the dog study was also increased relative kidney weights, with a NOAEL of 50 mg/kg-day (salt).

¹ The results of this literature review are available to the public upon request.

The Paynter *et al.* (1960) rat study has some deficiencies, including:

1. hematology was performed on only three males and three females,
2. clinical chemistry was not performed,
3. histology was performed on 50% of the survivors at each dose and
4. only a limited number of tissues were examined.

Nevertheless, these results were chosen by U.S. EPA as the critical study because the rat appears to be the more sensitive species compared to the dog. We have reviewed the original article by Paynter *et al.* (1960) and concur with U.S. EPA's rationale for selecting this study for risk assessment. Although only a summary of the data is available in this journal article, we agree with the use of 15 mg/kg-day (salt) as the unadjusted NOAEL for risk assessment.

DOSE-RESPONSE ASSESSMENT

Adjusted NOAEL

U.S. EPA's MCL (and MCLG) is 200 ppb for dalapon (U.S. EPA, 1992a). Serving as the basis for this MCL was a reference dose (RfD) of 0.03 mg/kg-day which, in turn, was based on an adjusted NOAEL of 8.45 mg/kg-day (rounded down to 8 mg/kg-day by U.S. EPA). The critical effect was an increased kidney-to-body weight ratio in male rats receiving 15 mg/kg-day commercial (65% pure) sodium dalapon (Paynter *et al.*, 1960).

The NOAEL was adjusted to correct for test compound purity and to convert the dose from the sodium salt into dalapon ion as follows:

$$\text{NOAEL (adjusted)} = \frac{(\text{NOAEL})(\text{purity})(\text{MW}_{\text{acid}})}{(\text{MW}_{\text{salt}})}$$

where,

$$\begin{aligned}\text{NOAEL} &= 15 \text{ mg/kg-day} \\ \text{purity} &= 65\% \\ \text{MW}_{\text{acid}} &= 143 \text{ g/mole} \\ \text{MW}_{\text{salt}} &= 165 \text{ g/mole.}\end{aligned}$$

Therefore,

$$\begin{aligned}\text{NOAEL (adjusted)} &= \frac{(15 \text{ mg / kg day})(0.65)(143 \text{ g / mole})}{(165 \text{ g / mole})} \\ &= 8.45 \text{ mg/kg-day} = 8 \text{ mg/kg-day (rounded).}\end{aligned}$$

U.S. EPA applied an uncertainty factor (UF) of 300 (100-fold for the use of an animal study and 3-fold for the limited quality of the database to calculate an RfD of 0.027 mg/kg-day.

U.S. EPA's MCL

The Drinking Water Equivalent Level (DWEL), which is calculated by multiplying the RfD (0.027 mg/kg-day) by body weight (70 kg for an adult male) and dividing by the assumed daily volume of

drinking water consumed (2 L/day for an adult), was 0.9 mg/L. U.S. EPA assumed a relative source contribution (RSC) of 20% (0.2) for dalapon (U.S. EPA 1992a). The MCL was calculated as the product of the DWEL multiplied by the RSC.

Therefore,

$$\begin{aligned}\text{MCL} &= 0.9 \text{ mg/L} \times 0.2 \\ &= 0.18 \text{ mg/L} = 0.2 \text{ mg/L (rounded)} = 200 \text{ ppb.}\end{aligned}$$

CALCULATION OF PHG

A public health-protective concentration (C, in mg/L) for dalapon in drinking water is calculated using the general formula for noncarcinogenic endpoints:

$$C = \frac{\text{NOAEL} \times \text{BW} \times \text{RSC}}{\text{UF} \times \text{L/day}} = \text{mg/L}$$

where,

$$\begin{aligned}\text{NOAEL} &= \text{No-observed-adverse-effect-level (8.45 mg/kg-day)} \\ \text{BW} &= \text{Body weight for an adult male (70 kg)} \\ \text{RSC} &= \text{Relative source contribution from drinking water of 80\% (0.8)} \\ \text{UF} &= \text{Uncertainty factor of 300 (10-fold for inter-species variation, 10-fold for human variability and 3-fold for insufficiencies in the database)} \\ \text{L/day} &= \text{Volume of daily consumption of drinking water (2 L/day).}\end{aligned}$$

Therefore,

$$\begin{aligned}\text{PHG} &= \frac{8.45 \text{ mg/kg-day} \times 70 \text{ kg} \times 0.8}{300 \times 2 \text{ L/day}} \\ &= 0.789 \text{ mg/L} = 0.79 \text{ mg/L (rounded)} = 790 \text{ ppb.}\end{aligned}$$

A PHG of 0.79 mg/L (790 ppb) is calculated for dalapon in drinking water.

RISK CHARACTERIZATION

Due to the low volatility and high polarity of dalapon, inhalation and dermal exposures from the use of contaminated water are expected to be negligible when compared to direct oral exposure. Accordingly, no attempt was made to account for these pathways in the calculation of the PHG. The database for dalapon is limited and the critical study in rats was conducted several years before guidelines were developed under pesticide law. Nevertheless, the rat study was selected over the dog study because the rat appears to be the more sensitive species compared to the dog.

An RSC of 80% was applied because dalapon is not currently used in agriculture and the sole source of exposure is expected to be from any residue possibly remaining in drinking water. This value is consistent with RSCs for other chemicals for which exposure comes exclusively from

drinking water. The RSC of 80% is however, different from U.S. EPA's value of 20% for relative source contribution. Therefore, the OEHHA PHG of 790 ppb is greater than U.S. EPA's MCL of 200 ppb.

There is a low confidence in the value for the PHG. Not only is the critical study deficient by today's standards (as noted above), but there are significant data gaps for this compound. Virtually all studies performed on dalapon (e.g., oncogenicity, reproductive, teratogenicity, gene mutation) do not meet current Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) standards. For example, in the Dow (1983) study, no individual body weights, histopathology, food consumption or time to death were reported. In addition, oncogenicity studies in the rat and rabbit teratogenicity studies do not exist. Because of the deficiencies in the critical study and the overall insufficiency of the database, an additional uncertainty factor of three was used to take these into account. This compound is not currently used in California agriculture, nor was it detected in the recent sampling for pesticide residues in California well water (DPR, 1997).

OTHER REGULATORY STANDARDS

In July 1992, U.S. EPA adopted 200 ppb for dalapon as both the MCL and the Maximum Contaminant Level Goal (MCLG) (U.S. EPA, 1992a). In March 1993, the Office of Environmental Health Hazard Assessment (OEHHA) proposed the adoption of U.S. EPA's MCLG of 200 ppb for dalapon as California's Recommended Public Health Level (RPHL). In addition, OEHHA recommended the adoption of this RPHL of 200 ppb to the California Department of Health Services (DHS) as the state MCL (DHS, 1993). A level of 200 ppb dalapon was adopted as the state MCL in 1994 (DHS, 1996).

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